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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/435,247	11/05/99	SORNASSE	T PA-0020 US

HM12/1001

Incyte Pharmaceuticals Inc
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EXAMINER	
SHEINBERG, M	
ART UNIT	**PAPER NUMBER**
1631	8

DATE MAILED: 10/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/435,247	Applicant(s) SORNASSE ET AL.	
	Examiner Monika B. Sheinberg	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *2-5 and 8-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6,7 and 18-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) ~~Paper No(s).~~ *1 sheet* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Restriction Election

Applicant's election with traverse of Group I (claims 1, 6-7, and 18-20), and nucleic acid SEQ ID NO: 219 in Paper No. 7, filed August 6, 2001 is acknowledged.

The traversal of Group I, is on the ground(s) that the invention of Group V, drawn to an isolated polypeptide or fragment thereof, is encompassed by the claims of Group I, which are drawn to polynucleotides. This is not found persuasive because the completely separate chemical types of the inventions of the nucleic acid and polypeptide Groups require separate and specific searches thus supporting the undue search burden if both were examined together. Additionally, polynucleotides and polypeptides have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examined together as compared to being searched separately. Therefore the claims that are under consideration are those of the elected Group I, claims 1, 6-7, and 18-20.

The traversal of the restriction to nucleic acid SEQ ID NO: 219, is on the grounds that claim 1 is drawn to a composition comprising a "plurality", "group", "set", or "combination of items. This is not found persuasive since the claim does not state a requirement that all the SEQ ID Nos or even a subset of these sequences have to be within the stated "plurality". The open claim language "comprise SEQ ID Nos: 1-516" includes any other polynucleotide sequence. Thus the SEQ ID No: 219 is one of the plurality with any other possible sequence other than SEQ ID Nos: 1-516.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112 and 101

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 1, 6-7, and 18-20 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

The claimed nucleic acids are not supported by a specific asserted utility because the disclosed nucleic acids are not linked to the diseases discussed within the specification on pages 17-18. The specification states that the nucleic acid compounds may be useful as hybridization probes on microarrays, which would be used for generic genetic analysis or gene expression analysis, including diagnosis of disease and treatment monitoring. The specification in fact summarized modern biotechnology generally but never connects any of the specifically elected sequences to any particular or specific utility. This wishlist desire for a utility for the claimed

sequences falls short of a readily available utility. The listed diseases are disclosed in a generic fashion that lacks demonstration of any relationship to the elected nucleic acid. These are non-specific diseases that are not particular or specific to the nucleic acids being claimed.

Further, the claimed nucleic acids are not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. For example, a nucleic acid whose expression is modulated by cytokines may be immobilized to a substrate, a microarray. The micorarray could then be used in conducting research to functionally characterize the nucleic acid and link it to a particular disease. The need for such research clearly indicates that the protein and/or its function is not disclosed as to a currently available or substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case the nucleic acids that are to be immobilized on a substrate produce a microarray, the final product, involving claimed nucleic acids having asserted or identified specific and substantial utilities. The research contemplated by applicant(s) to compose compositions containing nucleic acids that are those modulated by cytokines without a final link to a real world use, does not constitute a specific and substantial utility. Identifying and studying the properties of a nucleic acid itself or the mechanisms in which the nucleic acid is involved does not define a "real world" context or use. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of

record discloses or suggests any property or activity for the nucleic acid and/or protein compound(s) such that another non-asserted utility would be well established for the compounds.

The following is a quotation of the *first* paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 6-7, and 18-20 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial, and credible utility, or, alternatively, a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

The specification discloses SEQ ID NO: 219 which corresponds in some undefined way to cDNA/genomic DNA encoding human species of protein/nucleic acid. SEQ ID NO: 219 per se meet the written description and enablement provisions of 35 USC 112, first paragraph. However, claim 1 states that the polynucleotides of the composition "comprise" gene sequences, and fragments of sequences of SEQ ID NO: 219, and complements thereof, yet is not limited to only those sequences. In consequence, a plurality of sequences other than the elected or non-elected sequence could comprise the claimed composition. The claimed composition also includes possible flanking sequences. None of these additional sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim. This is a rejection based on a lack of WRITTEN DESCRIPTION.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons

of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Therefore, only SEQ ID NO: 219 but not the full breadth of the claims meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed is not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

The following is a quotation of the *second* paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 6-7, and 18-20 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 6-7, and 18-20 are vague and indefinite as to what is meant therein by the limitation "a complement". A possible interpretation is that the complement must be of the same length and be the full and exact complement of the recited SEQ ID NO: 219 sequence. Another interpretation is that any complement is meant including those with less than 100% complementarity, such as 90%, 50%, or even 10%. Clarification of the metes and bounds of the claim is requested via clearer claim wording.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. § 102(b) as being clearly anticipated by products O 6003 or O 3753 of The 1990 Sigma Chemical Catalog in view of the 35 U.S.C. § 112, second paragraph rejection set forth above concerning the metes and bounds of "a complement".

In The 1990 Sigma Chemical Catalog product O 7129, as a 17-mer oligonucleotide of poly dT nucleotides and product O 8254 is a 16-mer oligonucleotide of poly dT nucleotides. It is noted that these oligonucleotides are longer than 10 nucleotides in length and are about 88% and 93% identical to poly T segments or their complementary respective poly A segments of the instantly claimed nucleic acid. They also hybridize under high stringency conditions to their homopolymeric complementary segments. They thus anticipate instant claim 1 via segments therein which are poly A segments of 10 bases or longer, or 10 base segments with 6 or more A nucleotides therein, as are present in SEQ ID NO: 219.

No claim is allowed.

Declaration Objection

The oath/declaration was not signed and dated by the named inventors.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and

1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (703) 306-0511. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

September 27, 2001

Monika B. Sheinberg
Patent Examiner
Art Unit 1631

MBS

ARDIN H. MARSCHEL
PRIMARY EXAMINER